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PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 C.F.R. § 1.53(b)(2).

Attorney Docket Number: 38928.3.5

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TITLE OF INVENTION (280 characters max)

TESTING CONNECTOR FOR IMPLANTABLE LEADS

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ENCLOSED APPLICATION PARTS (check all that apply)

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[X] Drawings Number of Sheets: 15
[ ] Applicant(s) is/are entitled to small entity status in accordance with 37 CFR 1.27.
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[X] No. [ ] Yes. The name of the U.S. Government agency and the Government contract number are:

Respectfully submitted,

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PROVISIONAL APPLICATION FILING ONLY

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PROVISIONAL PATENT APPLICATION

TESTING CONNECTOR FOR IMPLANTABLE LEADS

FIELD OF THE INVENTION

The present invention relates generally to test connectors for implantable leads and the like. More particularly, the present invention relates to testing connectors suitable for attachment to an implantable medical lead connector to facilitate electrical testing of the implantable lead.

BACKGROUND OF THE INVENTION

Implantable medical devices, such as pulse generators, generally have at least one implantable lead that connects the device to a patient's heart. Typically, an implantable lead has a proximal portion including a connector adapted to be inserted within a corresponding port of the implantable device. The connector of the implantable lead can comprise one or more conductive interfaces on the exterior surface of the connector for making suitable connection to the contacts located within a corresponding port of the implantable device. Implantable devices and implantable leads are generally described in, for example, U.S. Patent No. 6,321,126 to Kuzma, entitled "Implantable Connector," and U.S. Patent No. 5,086,773 to Ware, entitled "Tool-less Pacemaker Lead Assembly," which are both incorporated herein by reference.

Generally, when an implantable medical device is placed into a human patient, testing procedures are conducted in order to determine, for example, suitable placement of the implantable lead, minimum defibrillation threshold, stimulation pulse output energy, lead conductivity, and electrode integrity among other things. In some procedures, the implantable lead is advanced into the patient's heart through a vein by a stylet or other suitable device. Once the distal end of lead contacts the heart, the physician generally tests the implantable lead to determine if the lead placement is acceptable, before connecting the proximal end of the lead to the implantable device. The testing of the lead can involve attaching the connectors on the proximal end of the implantable lead to an analyzer. During the testing procedure, it may be necessary for the physician to move the distal end of the lead by advancing or retracting the stylet, in order to locate an acceptable site for the placement of the implantable lead.

The above-mentioned tests associated with implantable leads are typically conducted in the operating room during the implant procedure. Consequently, several issues can arise with respect to the testing connector used to couple the implantable lead connector to an analyzer including, for

example, damage to the connector leads and two hand attachment of the testing connector to the implantable lead. Damage to the connector leads can increase the time and expense of the implant procedure, since a new lead may need to be used and routed inside the patient to a suitable location in the heart. Additionally, the physician will generally have one hand on the stylet or other actuating device connected to the lead during the procedure, and therefore may not have both hands available for operating and/or attaching a testing connector.

Due to the increasing number of medical procedures and treatment strategies employing implantable devices, it would be desirable to provide a testing connector for implantable medical leads that could address all of the above-mentioned limitations.

SUMMARY OF THE INVENTION

In a first aspect, the invention pertains to an apparatus for testing an implantable medical lead. The implantable medical lead has a proximal portion including a connector adapted to be inserted within a corresponding port of a medical device. The connector includes a plurality of conductive interfaces on an exterior surface of the connector. The testing apparatus comprises a handheld housing structure having a channel adapted to receive at least a portion of a connector of the implantable lead. In this embodiment, the testing apparatus further comprises one or more electrically conductive contact members positioned in a mating orientation with at least a portion of the conductive interfaces, such that the electrically conductive contact members can contact at least a portion of the conductive interfaces on the connector when the connector is positioned in the channel.

In a further aspect, the invention pertains to a method for testing an implantable lead. The method comprises establishing electrical connection with a portion of the conductive interfaces on a connector by positioning the connector in a testing apparatus, wherein the testing apparatus comprises a channel with one or more electrically conductive contact member positioned within the channel in a mating orientation with at least a portion of the conductive interfaces.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 shows an embodiment of a testing connector having a channel adapted to receive an IS-1 connector.

Fig. 2 shows an implantable lead comprising a connector positioned within the testing connector of Fig. 1.

Fig. 3 shows an embodiment of a testing connector comprising a unitary housing section.

Fig. 4 shows an embodiment of a testing connector having a channel adapted to receive an IS-4 connector.

Figs. 5-8 show an implantable lead with an IS-4 connector being positioned within a testing connector adapted to receive an IS-4 connector.

DETAILED DESCRIPTION OF THE INVENTION

Improved testing connectors comprise a handheld housing having a channel adapted to receive and hold the proximal end of an implantable lead. Due to the presence of the channel, the testing connectors can be coupled and uncoupled from an appropriate connector on the implantable lead without damaging the connector. The testing connectors further comprise one or more electrically conductive contact member positioned in a mating orientation with at least one of the conductive interfaces located on the connector of an implantable lead. Generally, the mating orientation is established by inserting the connector portion of an implantable lead into the channel of the screening connector. In some embodiments, the channel is adapted to receive and hold an IS-1 connector, while in other embodiments the channel is adapted to receive and hold an IS-4 connector.

As noted above, implantable leads associated with implantable devices are generally tested prior to final placement of the implantable lead within the patient. Since the testing procedure generally occurs in the operating room during a surgical procedure to implant the device and associated leads, damage to the connector during the testing procedure can increase the expense and time to complete the procedure. Additionally, the physician will generally have one hand on a stylet or other suitable device for changing the position of the distal end of the implantable lead. As a result, it is desirable in some applications to provide a handheld testing connector that can be coupled and uncoupled to a connector of an implantable lead with only one hand, and which will not damage the connector during the coupling/uncoupling process. As described herein, damage to the connector of an implantable lead can be prevented by employing a handheld connector with a channel adapted to receive a specific connector structure, such as an IS-1 connector. Additionally, the channel can allow a physician to couple and uncouple the testing connector from the connector using only one hand.

The testing connectors of the present invention generally comprise a channel or groove that is adapted to hold and receive the connector portion of an implantable lead. In some embodiments, the channel can be designed to receive an IS-1 connector, while in other embodiments the channel can be designed to receive an IS-4 connector. In some embodiments, the testing connector may comprise a unitary structure for the handheld housing with an opening at one end, while in other embodiments the testing connector can comprise a plurality of component pieces that form a handheld housing. The testing connectors can further comprise

one or more electrically conductive contact members positioned in a mating orientation with a portion of the electrical interfaces located along an exterior surface of a connector positioned within the channel.

Fig. 1 is a perspective view showing a testing connector 100 in accordance with an exemplary embodiment of the present invention. Testing connector 100 is shown comprising a handheld housing having a first side 102 and a second side 104. As shown in Fig. 1, first side 102 can comprise channel 106 and second side 104 can comprise channel 108. Channels 106, 108 are generally complimentary structures that are adapted to enclose a single connector when second side 104 contacts first side 102. In one embodiment, channels 106, 108 can be designed to receive a portion of an IS-1 connector. However, one of ordinary skill in the art will recognize that no particular channel shape is required by the present disclosure, and the design of the channel will be guided by the shape of the associated connector.

In some embodiments, first side 102 can be hingedly connected to second side 104 such that second side 104 can be rotated relative to first side 102 to enclose connector 112 of implantable lead 110. In some embodiments, second side 104 can be rotated up about 180 degrees relative to first side 102, while in other embodiments second side 104 may be rotated from about 50 to about 150 degrees relative to first side 102. One of ordinary skill in the art will recognize that additional ranges of rotation of the second side relative to the first side within these explicit ranges are contemplated and are within the scope of the present disclosure.

In some embodiments, second side 104 can further comprise a latch member, which can couple with a corresponding structure located on first side 102 to secure second side 104 to first side 102. The latch member and corresponding structure can be any mechanical system capable of coupling the second side of the testing connector to the first side of the connector. In some embodiments, the latch structure can be operated using only one hand, which permits a physician or other operator to have a free hand available during attachment of the testing connector to a connector. In some embodiments, latch member and corresponding structure can comprise, for example, a slot and protrusion mechanism or the like. One of ordinary skill in the art will recognize that additional latch and corresponding structures are contemplated and are within the scope of the present disclosure.

Referring still to Fig. 1, as described previously, testing connector 100 can comprise a first side 102 and a second side 104 with a channel 106, 108 formed into each side, respectively.

Due to the channel formed into the testing connector, the proximal end of an implantable lead can be inserted and/or removed from the testing connector without damaging the connector portion of the implantable lead. Additionally, the handheld design of the housing preferably permits a physician to attach testing connector 100 to an implantable lead using only one hand, which permits the physician to have a free hand to, for example, adjust the position of the distal end of the implantable lead.

Testing connector 100 can further comprise one or more electrically conductive contact member 114 positioned in a mating orientation with at least a portion of the conductive interfaces 116 located on an exterior surface of connector 112. Generally, the mating orientation is established when a connector of an implantable lead is positioned within an appropriate testing connector. As shown in Fig. 1, conduct contact members 114 are positioned such that when second side 104 is rotated to contact first side 102, contact members 114 can contact at least a portion of conductive interfaces 116. In some embodiments, contact members 114 extend though second side 104 such that a portion of the contact members are exposed on the exterior surface of testing connector 100 and are available for further connection. As shown in Fig. 2, the exposed portion 118 of contact members 114 can be connected to an analyzer or other test device by, for example, wires 120 or the like. One of ordinary skill in the art will recognize that the number and spacing of the electrically conductive contact members will generally be guided by the design of the intended connector.

Fig. 2 is an additional perspective view including testing connector 100. In the embodiment of Fig. 2, an implantable lead 110 is shown extending into a cavity defined by testing connector 100. Implantable lead 110 can be enclosed in testing connector 100, for example, by rotating second side 104 such that it contacts first side 102.

Fig. 3 is a perspective view of a testing connector 150 in accordance with an additional exemplary embodiment of the present invention. Testing connector 150 is shown comprising a handheld unitary housing structure having an opening 152 located at one end of testing connector 150. Opening 152 generally provides access for inserting the proximal end of implantable lead 154 into a channel formed in the interior of testing connector 150. Generally, the channel formed in the interior of testing connector 150 is designed to receive a specific implantable lead connector structure. In one embodiment, opening 152 and the associated channel can be designed to receive the proximal end of an implantable lead having an IS-1 connector, while in

other embodiments opening 152 and the associated channel can be adapted to receive an IS-4 connector. As shown in Fig. 3, testing connector 150 can further comprise a plurality of electrically conductive contact members 156 positioned to contact at least a portion of the conductive interfaces located on an exterior surface of a connector positioned in the channel of testing connector 150. Additionally, a plurality of wires 158 can connect the plurality of contact members 156 to an analyzer or other suitable testing equipment.

Fig. 4 is a perspective view showing a testing connector 200 in accordance with an additional exemplary embodiment of the present invention. Testing connector 200 is shown being adapted to receive an implantable lead 202 with an IS-4 connector 204. In some embodiments, connector 200 comprises a first side 206 and a second side 208. Generally, second side 208 is hingedly coupled to first side 206 such that second side 208 can rotate relative to first side 206 to enclose connector 204 within testing connector 200. As shown in Fig. 4, first and second sides 206, 208 can each comprise a channel 210, 212 adapted to receive a portion of an IS-4 connector. In one embodiment, channels 210, 212 can be complimentary structures designed to hold a single connector in a desired position. In some embodiments, channel 210 comprises electrically conductive contact members 214 and 216, and channel 212 comprises electrically conductive contact members 218 and 220. As shown in Fig. 4, in one embodiment, contact members 214, 216 can be aligned in a staggered configuration relative to contact members 218, 220. The electrically conductive contact members are generally aligned such that when connector 204 is enclosed within testing connector 200, the contact members are aligned in a mating orientation with at least a portion of the conductive interfaces 222 located on the exterior surface of connector 204.

Figs. 5-8 show an implantable lead 202 being enclosed within testing connector 200. As shown in Figs. 5-8, an implantable lead 202 can comprise a proximal portion having an IS-4 connector 204. The IS-4 connector 204 can be positioned in channel 210 located in first side 206 of testing connector 200 such that at least a portion of the conductive interfaces 222 located on connector 204 contact electrically conductive contact members 214, 216. Second side 208 of screening connector 200 can be rotated relative to first side 206 to enclose connector 204 within screening connector 200. Once second side 208 has been rotated to contact first side 206 and enclose connector 204, electrically conductive contact members 218, 220 can contact at least a portion of the conductive interfaces 222 located on an exterior surface of connector 204.

The housing of the testing connectors of the present invention can be composed of any non-conductive material suitable for use in medical procedures that does not damage the connector portion of the implantable lead. Suitable materials include homopolymers, copolymers, block copolymers and combinations thereof. Suitable polymers include, for example, polyethylene, polypropylene, poly(tetraflurorethylene), poly(vinylidene fluoride), poly(vinyl chloride), polyurethane, polycarbonate and blends and copolymers thereof. The electrically conductive contact members can be composed of any electrically conductive material, such as metals, metal alloys, conductive polymers, or combinations thereof. Suitable metals include nickel, aluminum, copper and combinations thereof. In some embodiments, the electrically conductive contact members can have a circular cross section, while in other embodiments the contact members may have an oval cross section, a rectangular cross section or the like. One of ordinary skill in the art will recognize that no particular cross sectional shape of the contact members is required by the present disclosure. The length of the contact members can be guided by the particular dimensions of the testing connector.

The housing portion of a preferred embodiment of the testing connector can be produced by any generally known plastic processing technique including, for example, extrusion, injection molding and compression molding. In some embodiments, the openings for the electrically conductive contact members can be formed integrally with the housing portion of the testing connector. In other embodiments, the openings for the contact members can be formed after the housing portion has been produced by, for example, drilling or the like. Generally, the electrically conductive contact members are inserted into the openings in the housing after formation of the housing.

The embodiments above are intended to be illustrative and not limiting. Additional embodiments are within the claims. Although the present invention has been described with reference to particular embodiments, workers in the art will recognize that changes may be made in form and detail without departing form the spirit and scope of the invention.

Representative statements of the invention:

1. The invention(s) described herein.

2. An apparatus comprising a housing defining a cavity capable of receiving a lead; and

a plurality of contacts capable of forming an electrical connection with the lead.

3. An apparatus comprising:

a housing having a first side and a second side;

the first side and the second side being movable relative to one another between a closed configuration and an open configuration;

the first side and the second side defining a cavity while the first side and the second side are deposed in the closed configuration;

the cavity having an interior dimension approximately corresponding to an outer dimension of a lead.

4. The apparatus described in 3, further including a plurality of contacts extending into the cavity.

5. The apparatus described in 4, wherein the contacts are axially spaced relative to one another.

6. The apparatus described in 4, wherein the contacts are spring biased so as to extend into the cavity.

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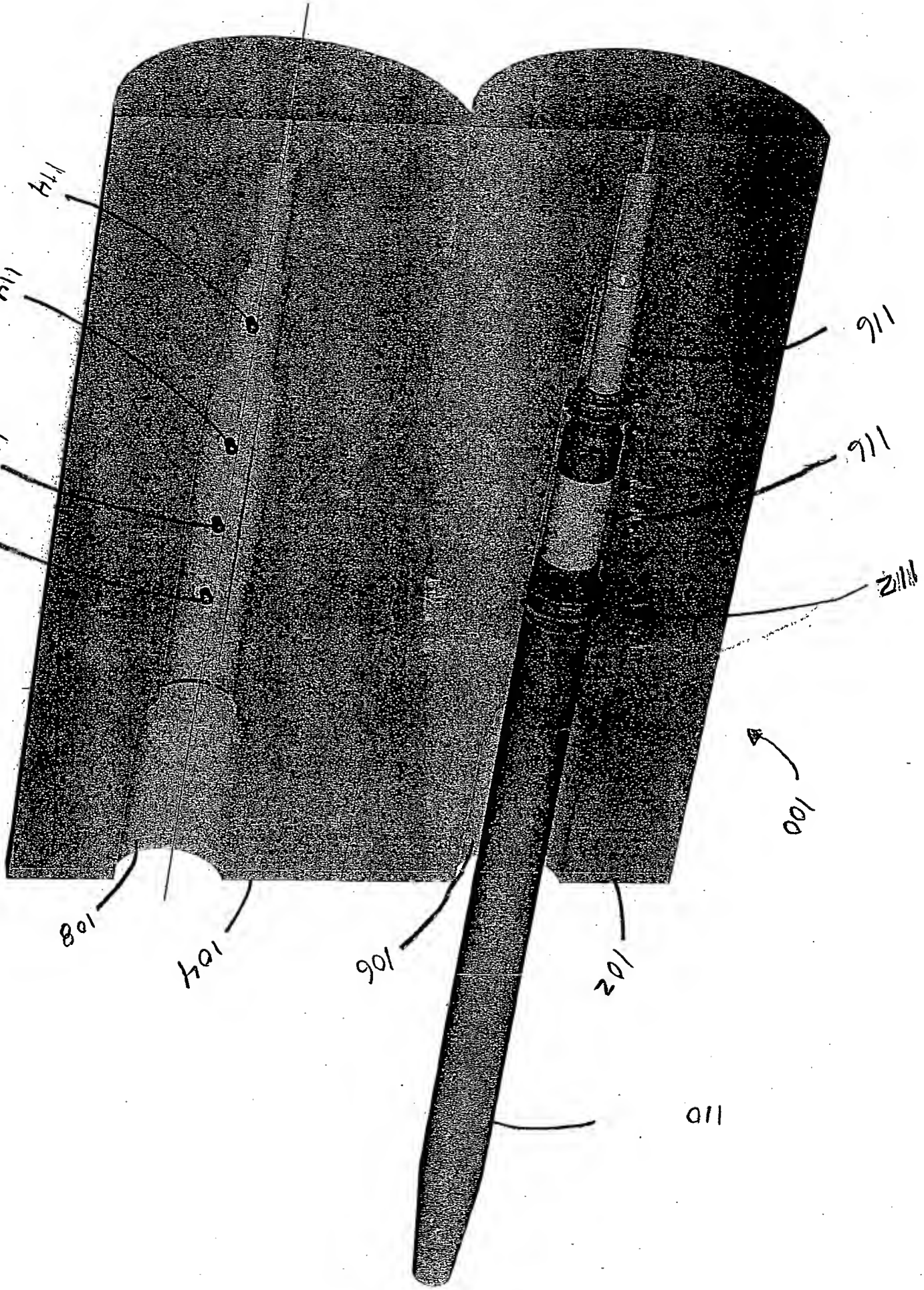
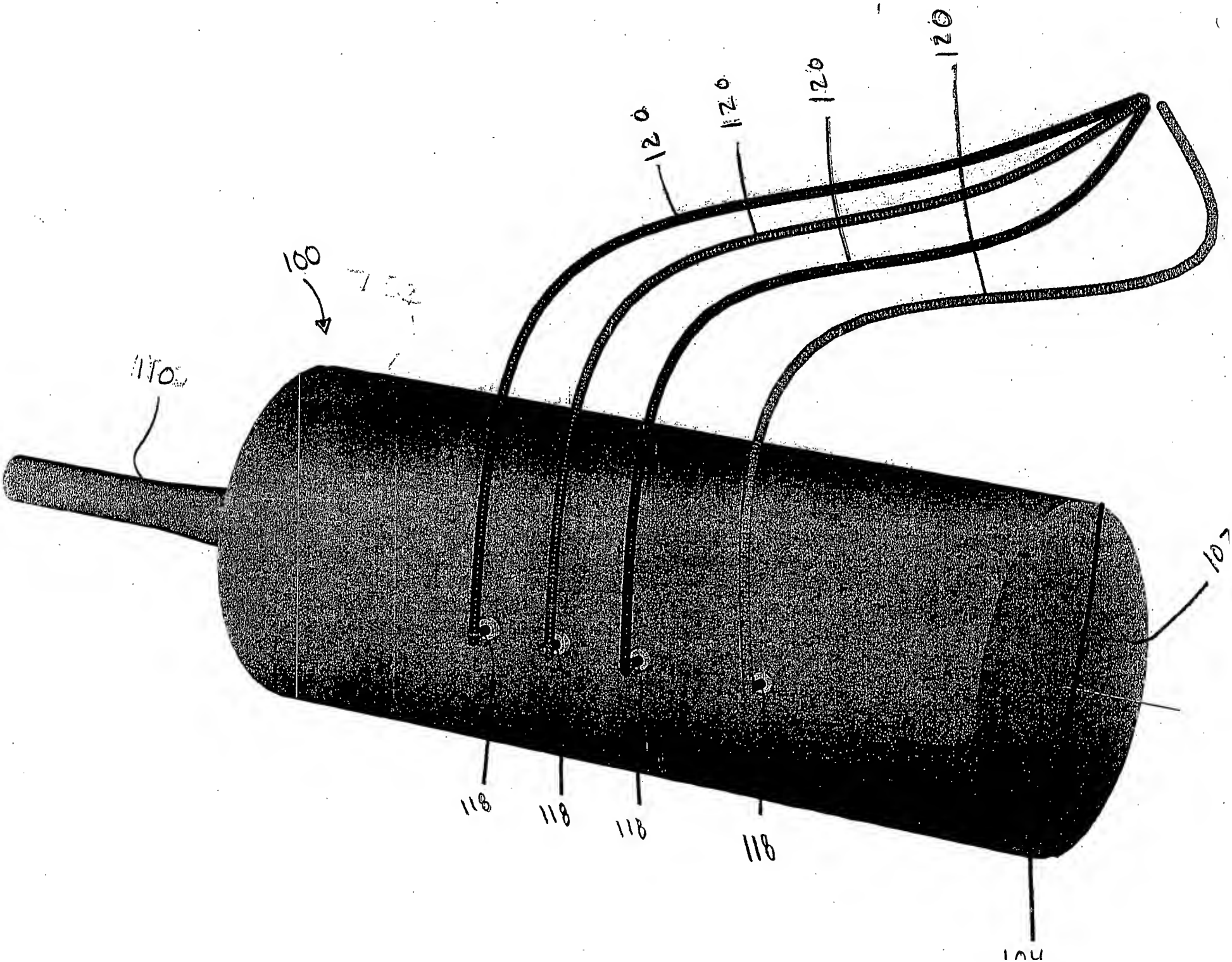


FIG. 1

FIG. 2



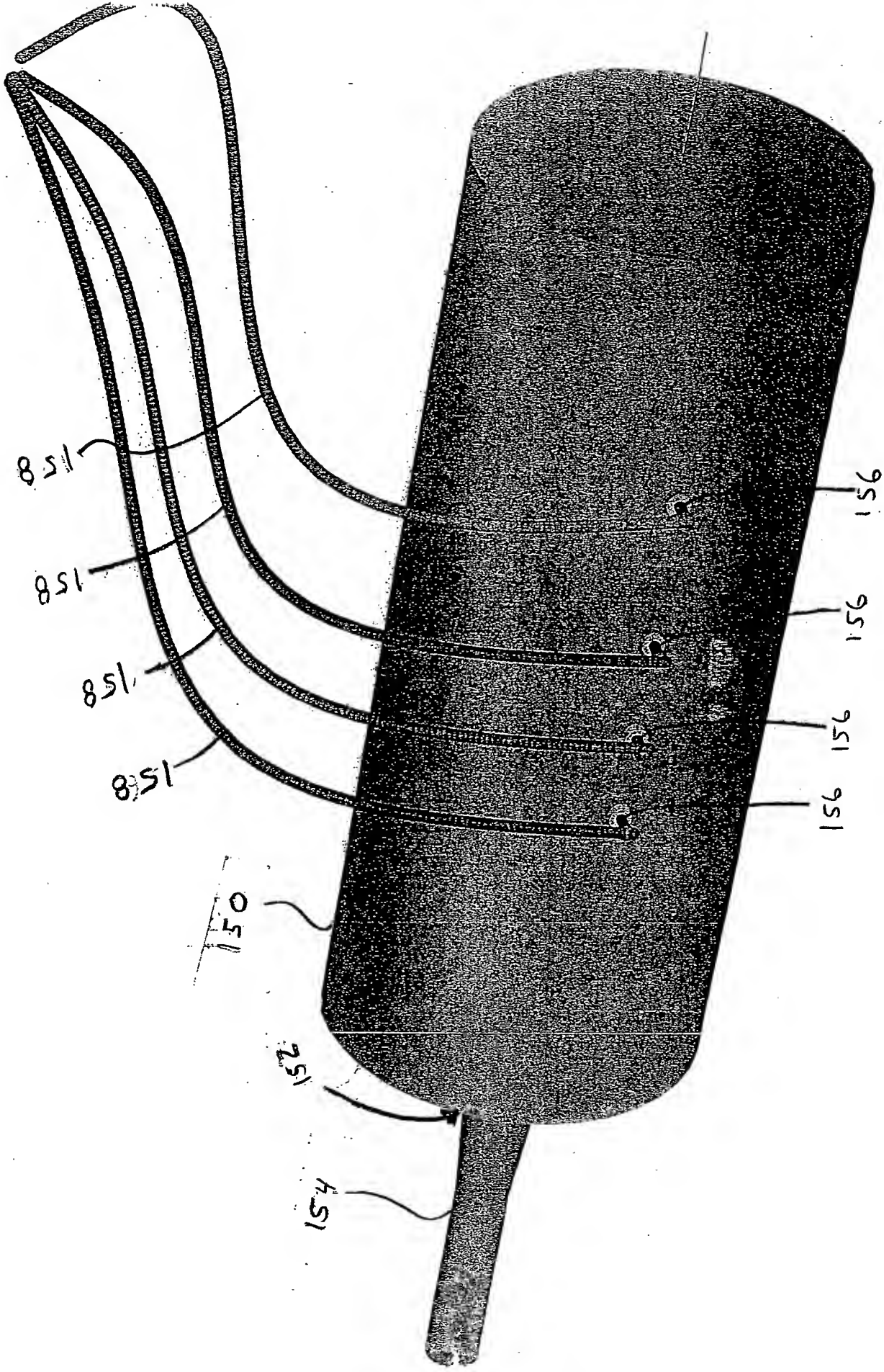


FIG. 3

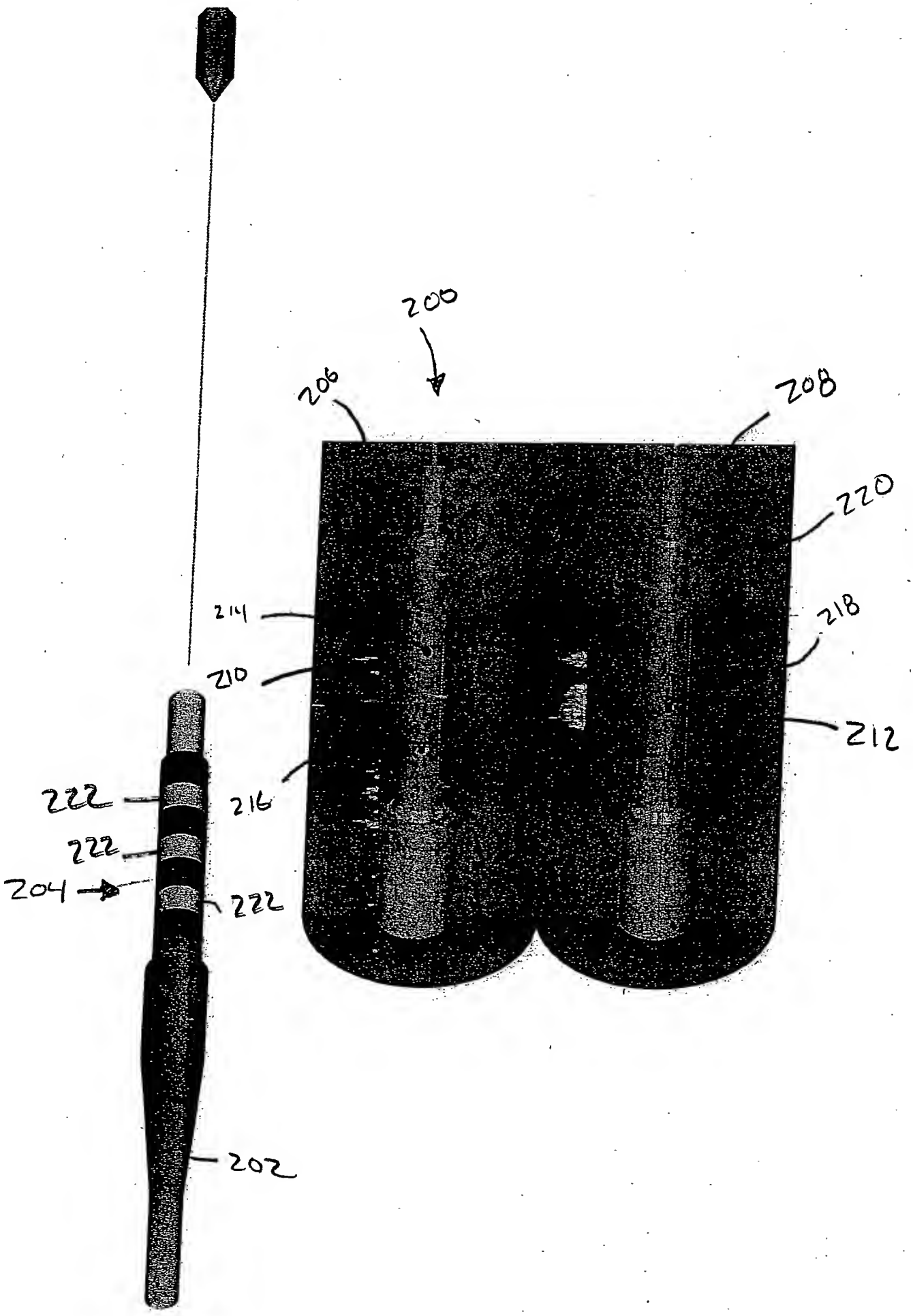


FIG. 4

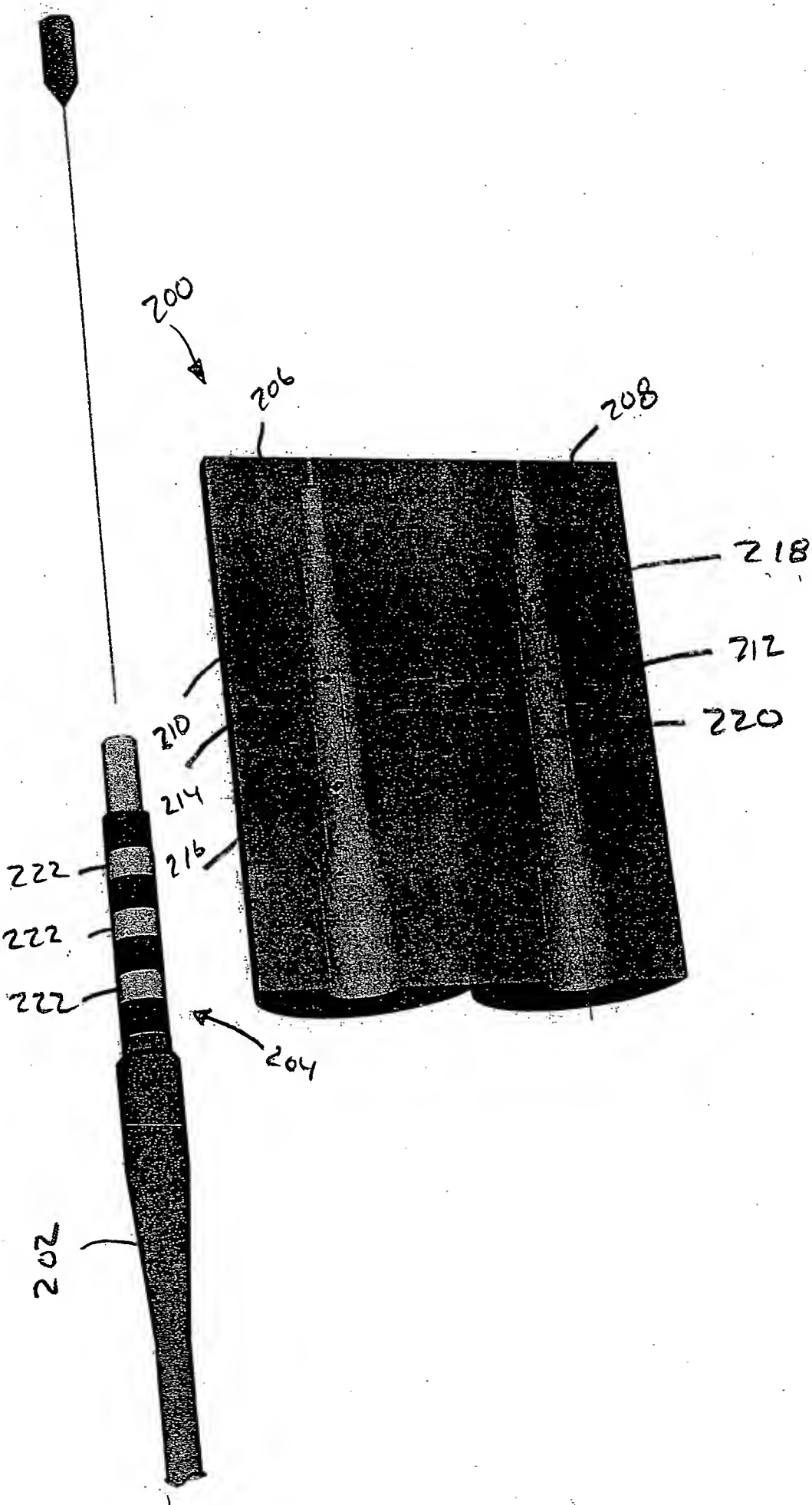


FIG. 5

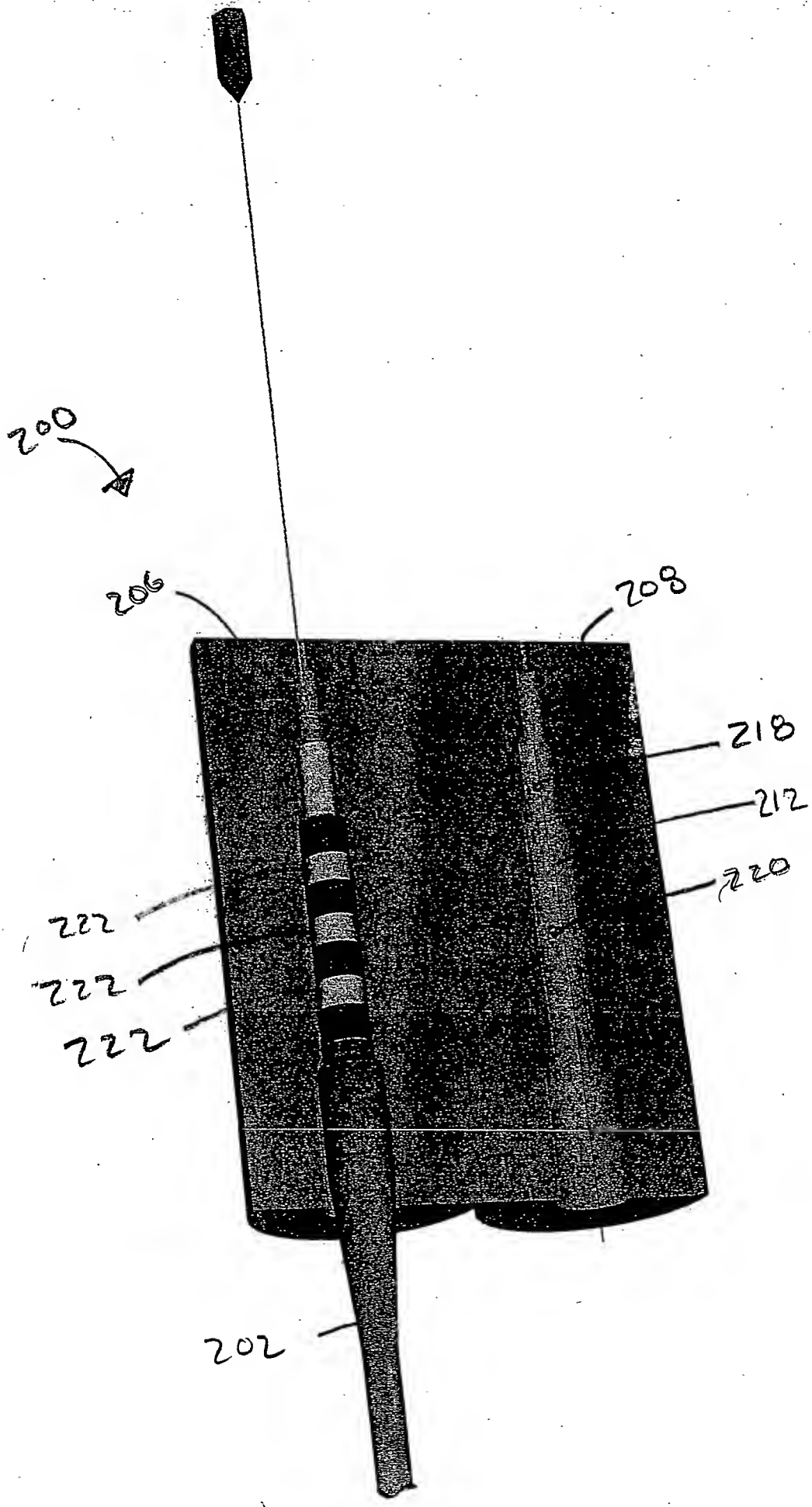


FIG. 6

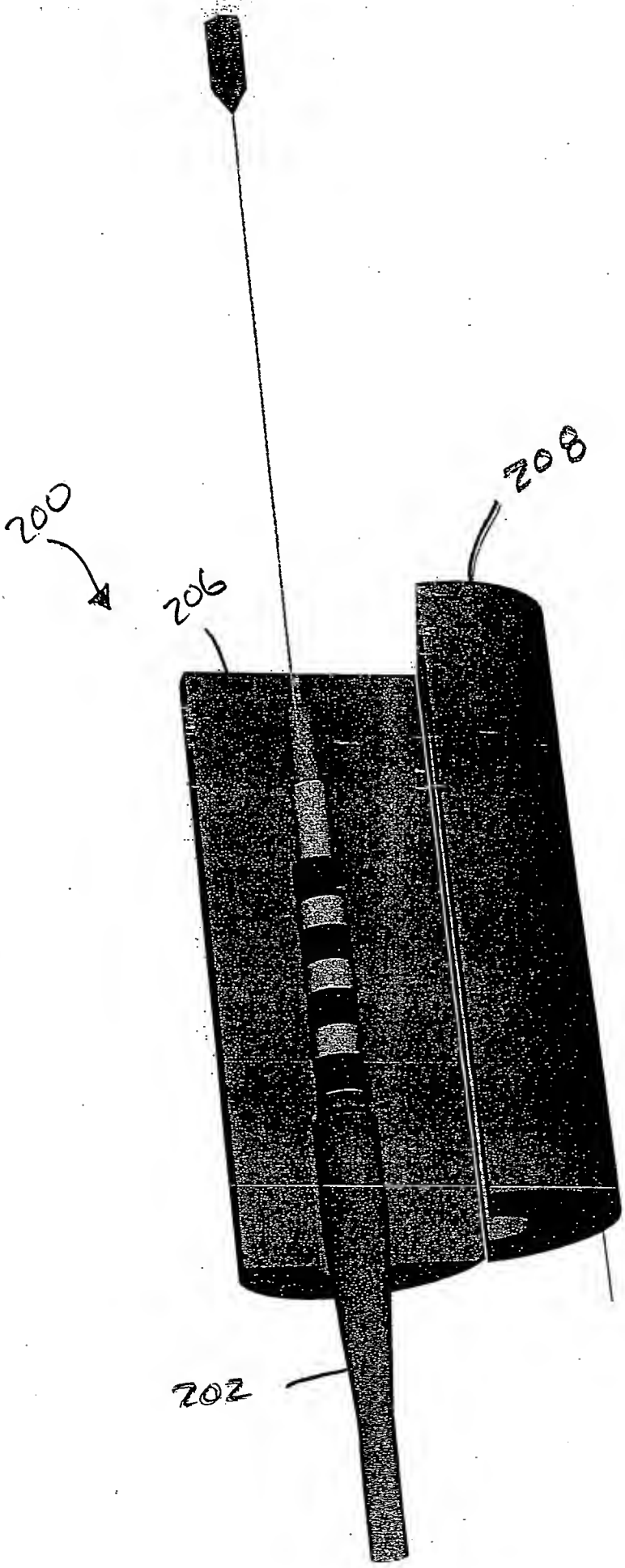


Fig. 7

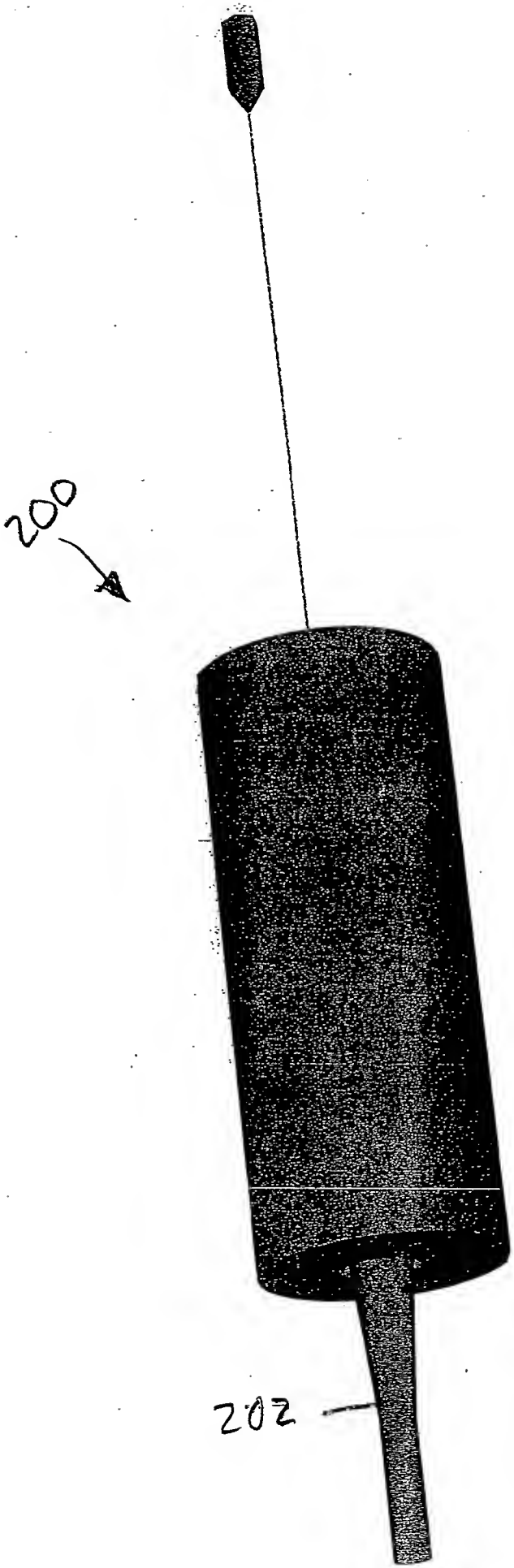
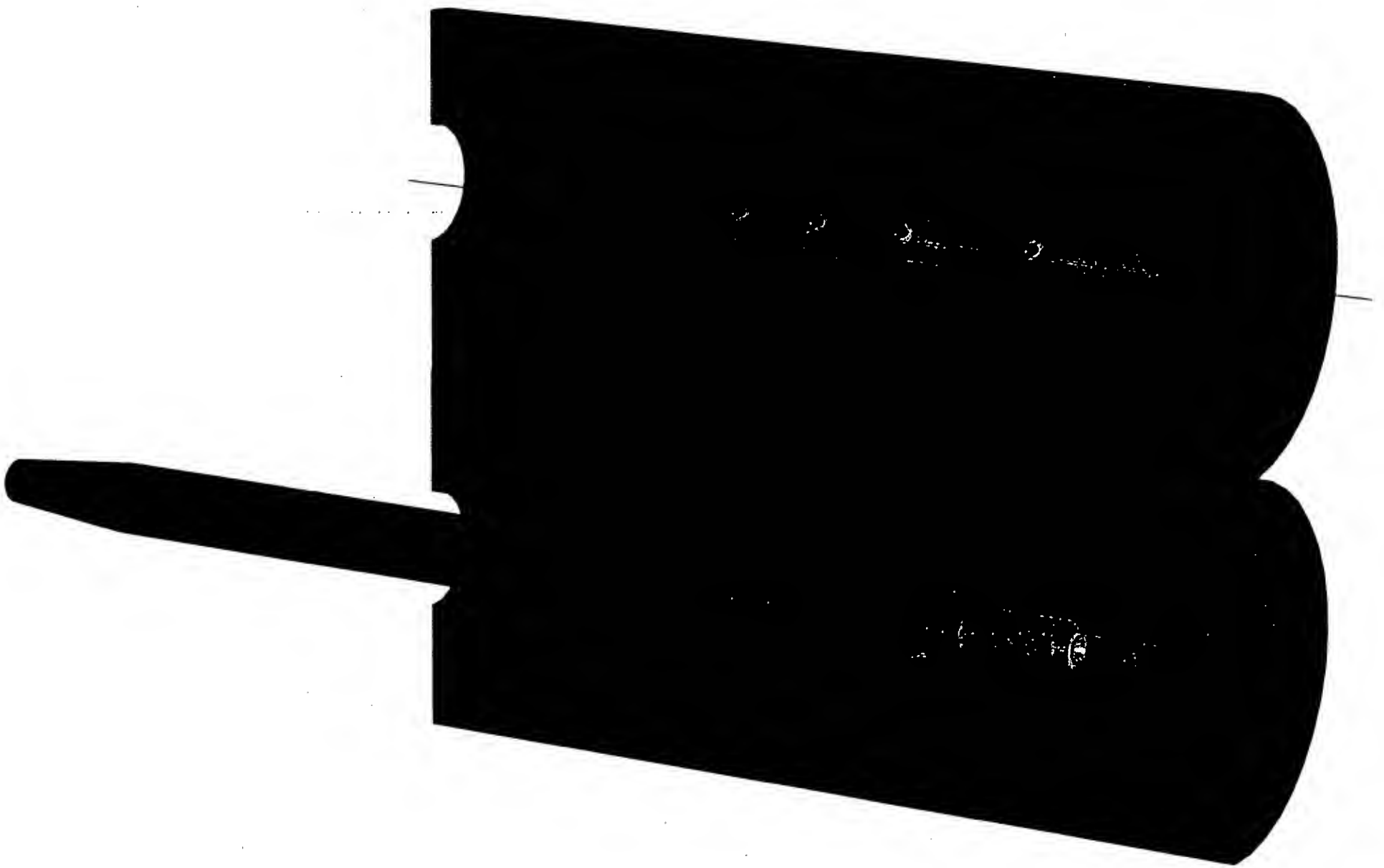
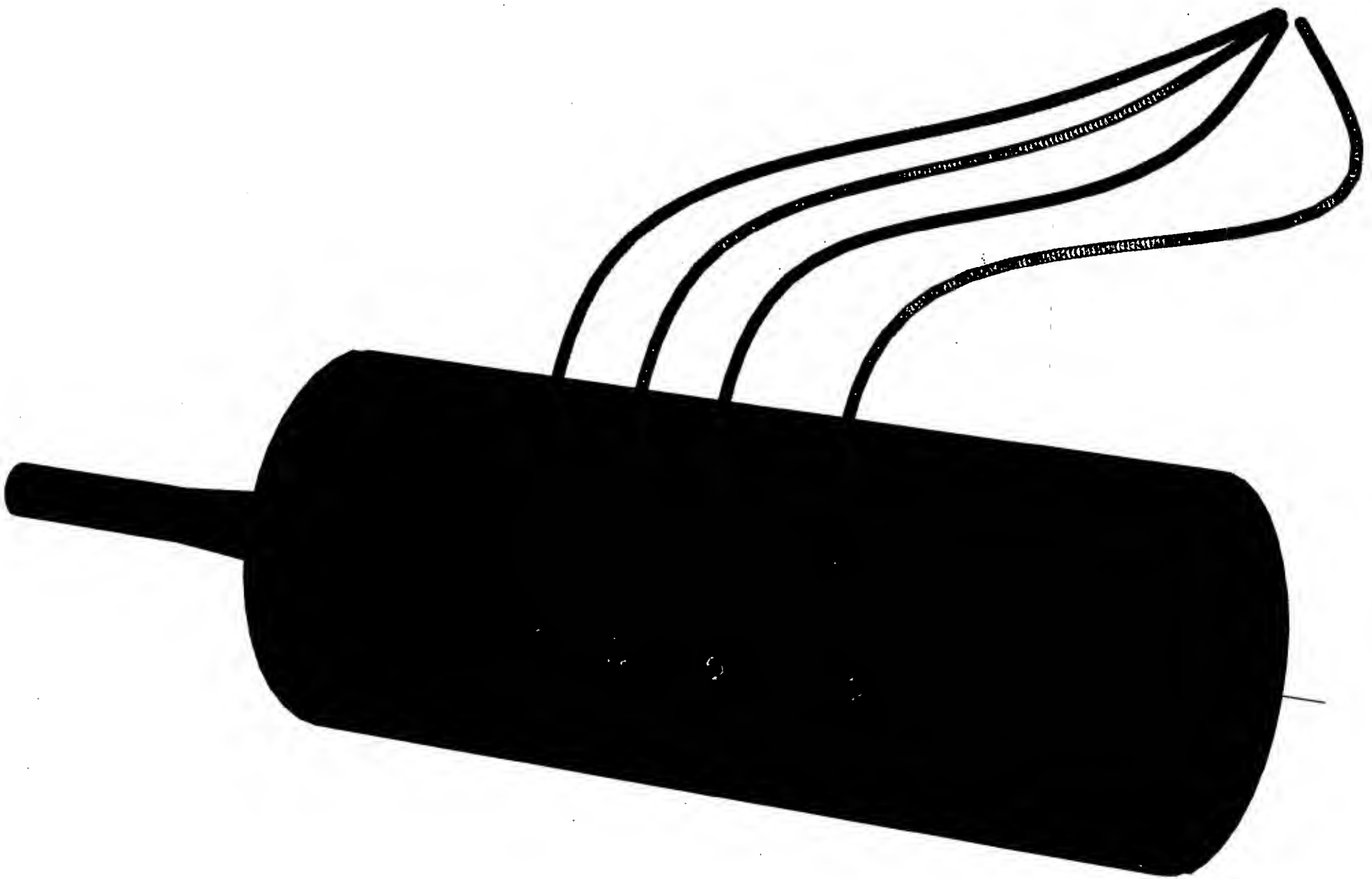


FIG. 8

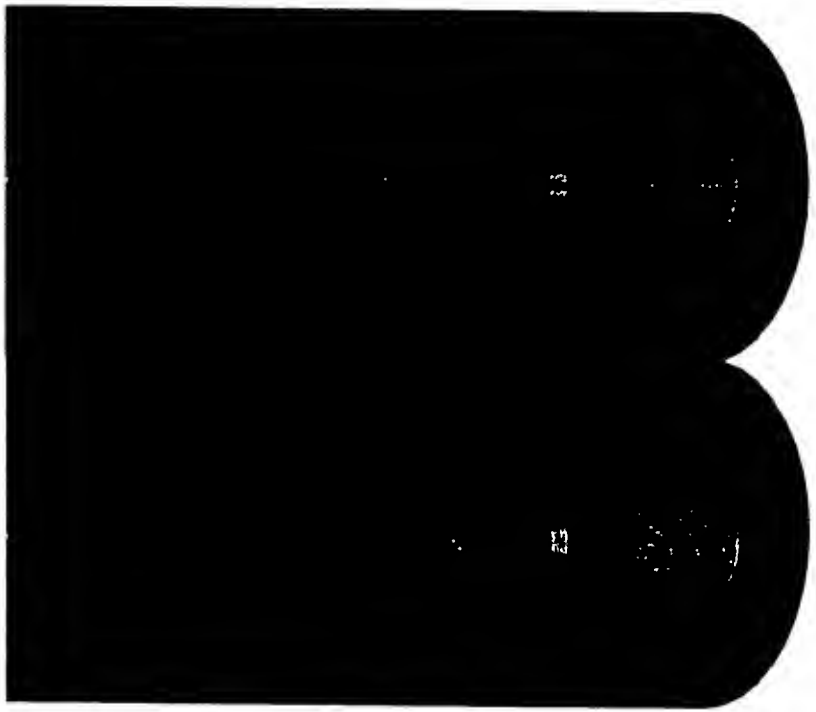
IS-1

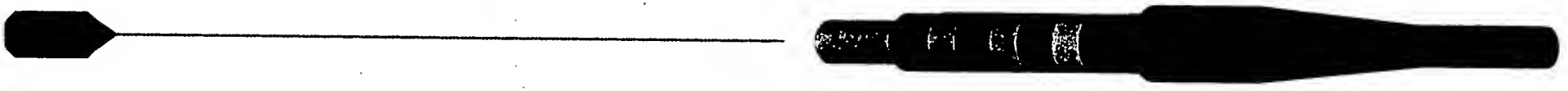


IS-4/IS-1

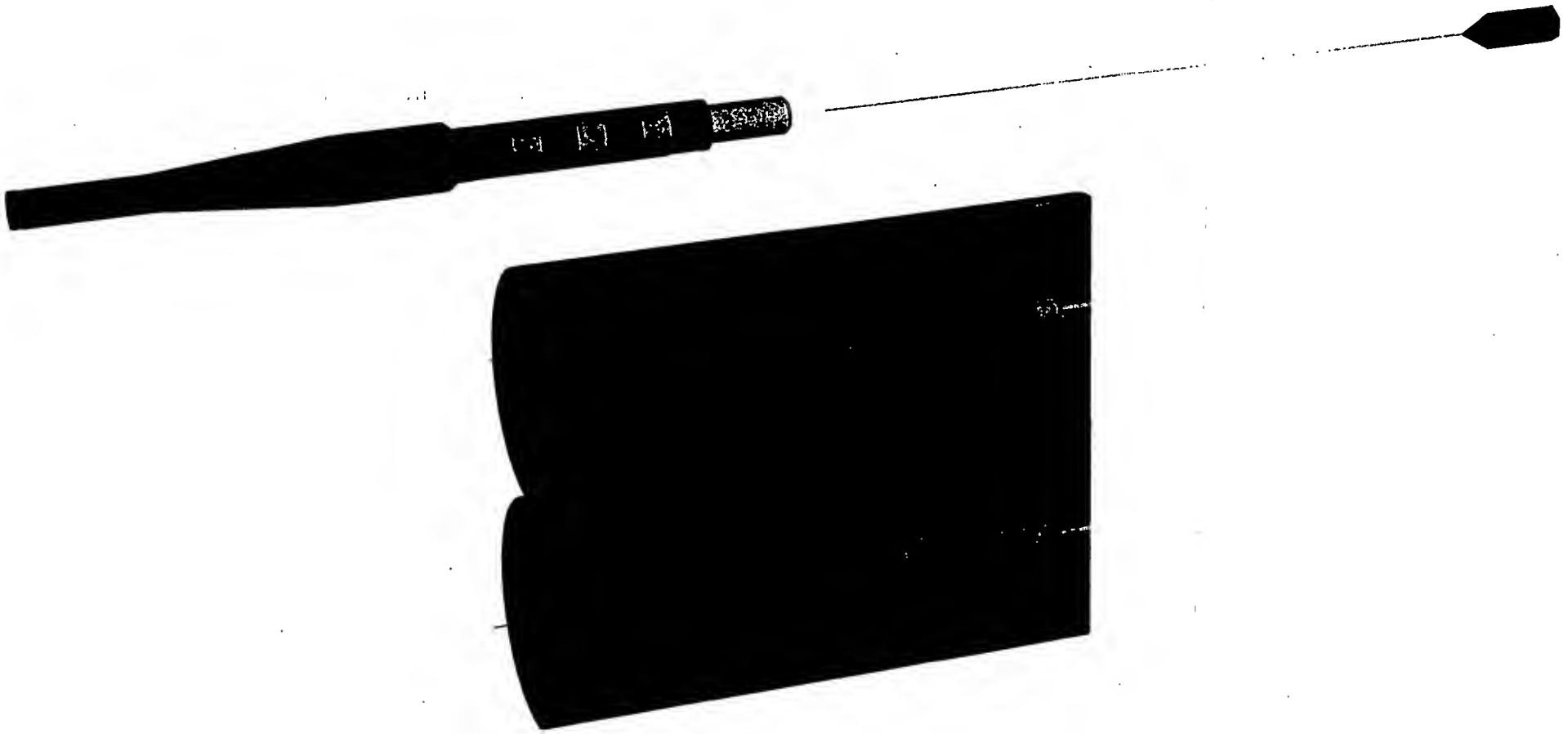


IS-4

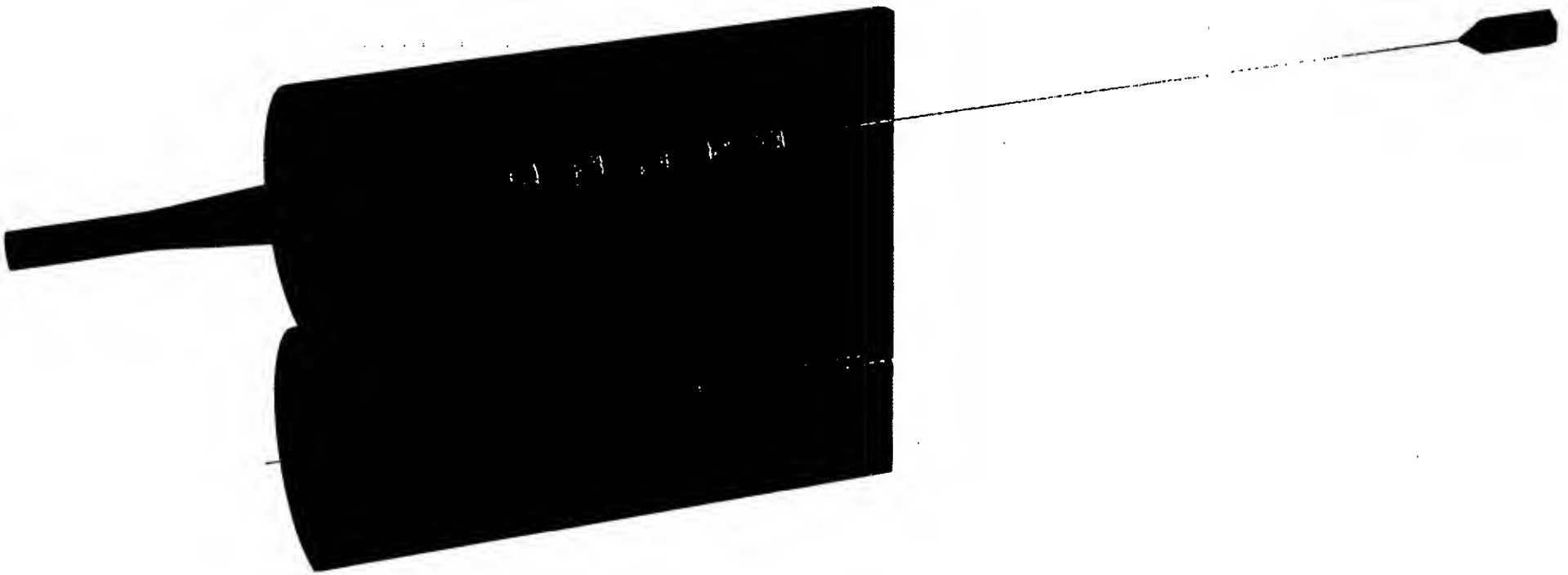




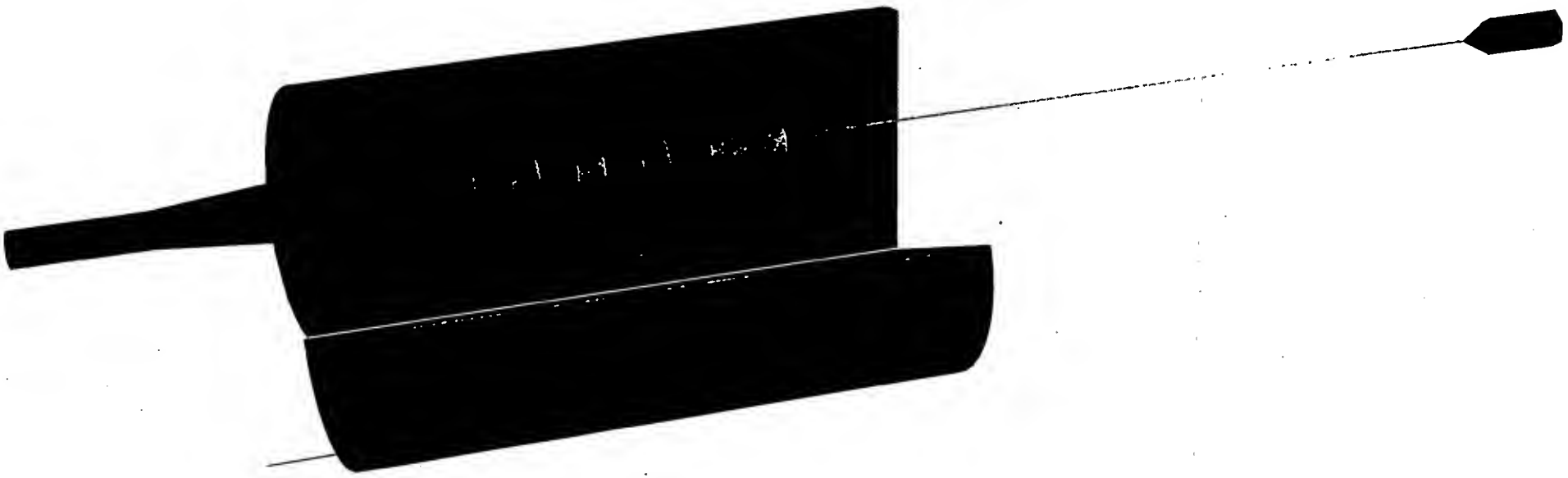
IS-4



IS-4



IS-4



IS-4